

1954. Misbranding of first aid kits. U. S. v. 594 First Aid Kits. Default decree of condemnation. Product ordered delivered to a charitable institution. (F. D. C. No. 20234. Sample No. 63642-H.)

LIBEL FILED: On or about June 12, 1946, District of New Jersey.

ALLEGED SHIPMENT: On or about April 9, 1946, by the H. P. Enterprise Co., from New York, N. Y.

PRODUCT: 594 *first aid kits* at Fair Lawn, N. J. Examination showed that each of the kits contained, among other items, vials of tablets designated as "Amphetamine Sulfate—5 MG.," "Atabrine Tablets," and "Wound Tablets." Analytical tests disclosed that the *wound tablets* contained sulfadiazine.

LABEL, IN PART: "First Aid Instructions Vest, Emergency, Sustenance Type C-1."

NATURE OF CHARGE. Misbranding, Section 502 (j), the products were dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the following labeling: (*Amphetamine sulfate tablets*) "Directions: Take one tablet if sleepy or two tablets if extremely fatigued. Repeat this dose in six hours if necessary but do not take more than six tablets in any one week," and (*wound tablets*) "Use—When Hit: Take all tablets. Drink lots of water. * * * Wounds—Take internally by mouth, followed by a large amount of water, 8 Sulfadiazine tablets."

Misbranding, Section 502 (f) (1), (*Atabrine tablets*) the labeling failed to bear adequate directions for use. The following directions in the labeling were not adequate directions for use in the prevention or treatment of malaria: "Use: For Prevention of Symptoms of Malaria. Take first dose (1 tablet) in the morning and second dose (1 tablet) in the evening after meals on two days of each week. Skip 2 or 3 days between days of taking Atabrine. Start to take Atabrine on first day you are in malarial area and continue to take it as long as you are in a malarial area * * * Malaria (Chills and Fever) (Prevention)—Take first dose of Atabrine (1 tablet) in morning and second dose (1 tablet) in the evening after meals on 2 days of each week. Skip two or three days between the days of taking Atabrine. Start to take Atabrine on the first days you are in a malarial area and continue to take it as long as you are in a malarial area."

DISPOSITION: July 23, 1946. No claimant having appeared, judgment of condemnation was entered and the products were ordered delivered to a charitable institution after the destruction of the labels under the supervision of the Food and Drug Administration.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

1955. Misbranding of Todd's Tonic Bitters, Todd's Laxanodine, and Todd's Iron-tone. U. S. v. Thomas I. Todd (Todd Medicine Co.). Plea of nolo contendere. Fine of \$300 and probation for 3 years. (F. D. C. No. 16584. Sample Nos. 87011-F, 87012-F, 87135-F.)

INFORMATION FILED: November 6, 1945, Middle District of Georgia, against Thomas I. Todd, trading as the Todd Medicine Co., Athens, Ga.

ALLEGED SHIPMENT: On or about July 27 and November 25, 1944, from the State of Georgia into the State of Michigan.

PRODUCT: Analyses disclosed that the *Tonic Bitters* consisted essentially of sodium salicylate, extracts of plant drugs, including a laxative drug and a bitter drug, alcohol 3.94 percent by volume, and water; that the *Laxanodine* consisted essentially of sodium salicylate, extracts of plant drugs, including a laxative drug and a bitter drug, and water; and that the *Iron-tone* consisted essentially of extracts of plant drugs, including a laxative drug and a bitter drug, a small proportion of salicylic acid, iron acetate (approximately 1.1 percent), and water.

NATURE OF CHARGE: *Tonic Bitters*, misbranding, Section 502(a), certain statements on the label of the article, and the statement in the circular enclosed in the package containing the article, "Good Health Is Worth More Than Riches or Gold," were false and misleading since they represented and suggested that the article was a tonic, diuretic, and alterative; that it would be efficacious in the cure, mitigation, treatment, and prevention of diseases of the stomach, kidneys, bladder, bowels, and blood, rheumatism, lumbago, faulty elimination of the kidneys, and affections of the urinary tract; that it was an efficacious tonic to the stomach and alimentary tract; that it would restore vigorous

*See also No. 1954.